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| 10/577,054 | 04/24/2006 | Kim Bager | P71223US0 | 9927 |
| 13% 7590 01/21/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,054

Applicant(s)

BAGER ET AL.

Examiner

Ginger T. Chapman

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 9 and 11-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 10 and 14-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/24/2006 & 9/11/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II, claims 7-8, 10, 14, newly added 15-20, in the reply filed on November 3, 2008 is acknowledged. The traversal is on the ground(s) that Group III is also directed to a two-part ostomy wafer having a weld zone between surfaces. This is not found persuasive because the special technical feature of Group II is a weld zone extending over a first distance in a radial direction and over a second distance extending over the zone and the second distance extending in the radial direction and being at least 1.5 times the first distance; the special technical feature of Group III is one or more surfaces or elements of a first surface of a second part being aligned with at least part of weld zones. Therefore, the special technical feature inking the inventions, an ostomy wafer, does not define a contribution over the prior art and no single general invention concept exists. Therefore the restriction is appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Status of the claims

2. Claims 15-20 are added; claims 7-11 and 14 are amended; claims 1-20 are pending in the application; claims 1-6, 9 and 11-13 are withdrawn from consideration as being drawn to a nonelected invention.

Drawings

3. Figures 5A and 6A, see Specification p. 9, l. 20 and ll. 29-30, should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g).

Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(l) because all drawings must be made by a process which gives them satisfactory reproduction characteristics. Every line, number, and letter must be durable, clean, black, sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

§ 1.84 Standards for drawings.

(l) Character of lines, numbers, and letters. All drawings must be made by a process which will give them satisfactory reproduction characteristics. Every line, number, and letter must be durable, clean, black (except for color drawings), sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

(p) Numbers, letters, and reference characters.

(1) Reference characters (numerals are preferred), sheet numbers, and view numbers must be plain and legible, and must not be used in association with brackets or inverted commas, or enclosed within outlines, e.g., encircled. They must be oriented in the same direction as the view so as to avoid having to rotate the sheet. Reference characters should be arranged to follow the profile of the object depicted.

(3) Numbers, letters, and reference characters must measure at least .32 cm. (1/8 inch) in height. They should not be placed in the drawing so as to interfere with its comprehension. Therefore, they should not cross or mingle with the lines. They should not be placed upon hatched or shaded surfaces. When necessary, such as indicating a surface or cross section, a reference character may be underlined and a blank space may be left in the hatching or shading where the character occurs so that it appears distinct.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 7-8, 10, 15, 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al (US 2003/0093042 A1).
7. With respect to claim 7, as best depicted in Figures 1 and 2a, Leisner discloses a body side mounting wafer 20 for attachment to a person and an ostomy bag 10, the wafer comprising a first part 21 having a first surface 24 (fig. 1) 200 (fig. 2a) adapted to be attached to a person and a second opposite surface 25; a second part 30 (fig. 1), 100 (fig. 2a) having a first surface 37 adapted to be attached to ostomy bag 10 and a second opposite surface 36; one or more welds 205 (fig. 2a) formed at one or more zones between the second surfaces of the first and second parts [0030] fig. 2a; at least one or more welds 205 extending over a first distance in a radial direction [0031].
8. Leisner discloses the claimed invention except for expressly disclosing weld zones. Leisner teaches the second surfaces of the parts are welded at location 205, therefore the location of the welds are considered the zones of welding, i.e. weld zones.
9. Leisner discloses the claimed invention except for expressly disclosing the first surface of the second part being substantially smooth at the weld zone and over a second distance extending over the weld zone, the second distance being at least 1.5 times the first distance. Leisner teaches weld zone 205 radially extending varying distances (figs. 2a-2f). With respect to the limitation of smoothness, as best depicted in Figures 2a, 2b, 2c, and 2e, Leisner teaches that the surface has transition zones which are not smooth: zone 106 (fig. 2a), zone 116 (fig. 2b), zones 121 and 122 (fig. 2c), zone 143 (fig. 2e). Leisner teaches that the zones which are not smooth are adjacent the weld zones. Therefore, relative to the transition zones, the surfaces at the weld zones are substantially smooth for the distances extending to the transition zones. Therefore it

would have been obvious to one having ordinary skill in the art at the time the invention was made to form the surfaces of Leisner substantially smooth at the weld zones since Leisner states, at [0031], that this provides a good transfer of heat in a heat welding process that assures a bond with reduced risk of damage to the first and second parts forming the body side wafer.

10. With respect to the limitation of the second distance extending being at least 1.5 times the first distance, as best depicted in Figures 2a, 2b, 2c, and 2e, Leisner teaches the second distance extends in the radial direction [0031] over ranges of distances relative to the first distance.

Therefore it would have been obvious to one having ordinary skill in the art to form the second distance of the claimed value since Leisner states, at [0031], that the weld zone, i.e. the portion of the second part 100 joined to the portion of the first part 200 may be attached at a distance extending a distance from an inner edge and also extending a greater extent, thereby teaching the general conditions of the weld zone extending varying distances in the radial direction.

11. Leisner teaches that the bond formed between the parts may correspond to smaller or larger areas of the parts [0027], and teaches at [0036-7] that it is desirable to allow the inner portion of the second part free to move relative to the first part in order to be less rigid and thus better conform to the movements of the wearer thereby reducing leakage [0039 and 0027].

Leisner teaches a variety of distances and configurations of the weld zones joining the first and second parts, but is silent on particular values [0027, 31].

12. One of ordinary skill in the art would recognize that a larger weld zone would result in providing a greater area of attachment at the joined portions, i.e. a more secure join, but would result in increasing the rigidity of the parts, i.e. reduce the ability of the un-welded inner portions of the parts to flex or move relative to each other. One of ordinary skill in the art would also

recognize that a smaller weld zone would result in providing a less secure attachment but would reduce the rigidity of the joined parts and allow the un-welded portions of the parts to flex or move relative to each other. Therefore the distance the weld zone extends is a balance between providing a secure attachment while permitting the parts to flex or move with the movements of the wearer. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the distance of the weld zone extending the claimed distance to provide optimum securement and flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

13. With respect to claims 8 and 20, Leisner discloses the embodiments wherein no part of the first surface of the second part 100 (figs. 2d and 2f), in a cross section along the radial direction and over the second distance, has any part deviating from a flat shape. With respect to the values of 2 mm of the first surface deviating more than 0.2 mm from the flat shape, Leisner teaches, at [0036, 27 and 31], that the distance values can be smaller or larger while still providing secure attachment between the parts and also providing sufficient flexibility that the parts can move with the movements of the wearer. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the parts having the claimed distances to provide optimum attachment and flexibility since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

14. With respect to claims 10 and 15, as best depicted in Figures 1 and 2a, Leisner discloses the first part 21, 200 has a first opening 22; the second part 30, 100 has a second opening 31; the zones being positioned in a vicinity of the edge 205 of the second opening [0031].

15. With respect to claim 17, as best depicted in Figure 2c, Leisner discloses multiple welds (at base of 125 and 126); the examiner notes that multiples of the same structure do not lend additional patentable weight and is an obvious modification.

16. With respect to claim 18, as best depicted in Figures 2a-2f, Leisner teaches the first part 100 having a general thickness profile [0031-2; 34-5] where the actual thickness, over the second distance deviates in a range of percentages from the general thickness of the general thickness profile over the distance, thus disclosing the general conditions of the claim, but Leisner does not specify any particular values for the deviations. Leisner teaches, at [0032, end of paragraph], that increased thickness permits improved handling during mounting and bag exchange procedures, and at [0039] that reduced thickness about the inner portion of the part in the vicinity of the opening permits the wafer to move with the stoma during the movements of the wearer. Therefore the thickness of the part along the second distance can be optimized for handling and flexibility and as such it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize these parameters. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

17. With respect to claim 19, Leisner teaches the first surface 37 of the second part 31 is adapted to form an adhesive coupling to the ostomy bag 10, and the surface is so smooth that the adhesive and a component of the bag holding the adhesive is fully capable of taking up variations of the surface from the intended shape of the surface [0026; 0008].

18. The examiner notes the use of relative and functional language in the claim and contends that the surface of Leisner is fully capable of performing the intended function.

19. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leisner et al (US 2003/0093042 A1) in view of Bager et al (WO 02/00144 A1).

20. With respect to claim 14, Leisner discloses the claimed invention except for expressly disclosing an apparatus for assembling the wafer. As best depicted in Figure 5 (p. 20, ll. 6-8), Bager teaches an apparatus for assembling a wafer including a fastening element for maintaining the parts in a predetermined abutting relationship (p. 9, ll. 12-25); and an element for providing electromagnetic radiation to the zones to form welds (p. 12, ll. 25-33). Therefore it would have been obvious to one having ordinary skill in the art to provide an apparatus for assembling the wafer of Leisner as taught by Bager since Bager states, at p. 21, l. 11, that the benefit of using such an assembly is that it permits the area to be welded resulting in a weld.

21. With respect to claim 16, Leisner discloses the claimed invention except for the weld is a laser weld. Leisner teaches welding around the opening of the wafer, thus providing motivation for a weld around the opening [31]. Bager, at p. 7, l. 33 to p. 8, l. 8, teaches a laser weld. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the weld of Leisner as a laser weld as taught by Bager since Bager states, at p. 8, ll. 26-27, that this permits the weld to be placed with great precision at the location to be welded.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 7 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 7,244,482 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the issued claims are drawn to the substantially identical structure recited in terms of the laser welded surfaces being capable of absorbing laser light.
24. Claims 7 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 34 of copending Application No. 11/578,366 (US 20080176023 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and co-pending claims are drawn to the substantially identical structure with the laser weld described in terms of the absorption coefficient of the surfaces which are welded.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 7 and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 36 of copending Application No. 11/826,266 (US 20070262479 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and co-pending claims are drawn to the substantially identical structure with the welded surfaces described as welded layers.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
27. EP 1 108 404 A1 (Watley et al) "X" reference in ISR for corresponding PCT application WO 2005/039861 A2.
28. WO 96/38106 (Olsen) teaches an ostomy bag adhesive coupling wherein a smooth surface is so smooth that the adhesive is able to take up any variations in the surface from the intended shape of the surface.
29. WO 02/00144 A1 (Bager et al) teaches methods for laser welding surfaces of an ostomy wafer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
01/13/09

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